

Application No. 10/568,329
December 14, 2009
Response to Office Action Dated July 14, 2009

AMENDMENTS TO THE CLAIMS:

Claim 1 (Currently Amended). A process for the preparation of a recombinant polypeptide, comprising the steps of

a) fermenting a prokaryotic host cell in a fermentation medium, the host cell comprising a periplasm and being transformed with a recombinant expression system capable of effecting secretion of the polypeptide into the periplasm of the host cell, wherein the fermentation is performed in the fermentation medium under conditions such that the polypeptide is secreted into the periplasm of the host cell,

b) interrupting fermentation the further processing of the host cell in the fermentation medium prior to completion of the fermentation and maintaining the host cell on hold in the medium under defined conditions of temperature and pH prior to extraction of the polypeptide, and under non-lethal conditions at a temperature of from about 4°C to about 25°C at a pH of from about 4 to about 10 and for a time ranging from at least about 1 hour to about 72 hours so as to ensure that the integrity of polypeptide secreted into the cell periplasm in the cell in the fermentation medium is maintained while substantially avoiding any further fermentation of the medium;

c) concentrating the fermentation medium by centrifugation or micro filtration prior to and/or in conjunction with interruption of the fermentation interruption of further processing in step b), and

d) recovering polypeptide from cell periplasm in the concentrated fermentation medium following interruption of fermentation in step b), wherein the yield of polypeptide recovered from the periplasm is increased compared to the polypeptide yield of processes in which fermentation is not interrupted, but is instead taken to completion.

Claim 2-9 (Cancelled).

Claim 10 (Currently Amended). A process according to claim 1, wherein the pH of the fermentation medium is maintained at a pH of ranging from about 5 to about 9 during step b).

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Claim 11 (Currently Amended). A process according to claim 1, wherein the pH of the fermentation medium is maintained at a pH of ranging from about 6 to about 8 during step b).

Claim 12 (Previously Presented). A process according to claim 1, wherein the pH of the fermentation medium is maintained at about 7 during step b).

Claims 13-15 (Cancelled).

Claim 16 (Previously Presented). A process according to claim 1, wherein step b) is performed in a fermenter.

Claim 17 (Previously Presented). A process according to claim 1, wherein the prokaryotic host cell comprises a Gram-negative bacterium.

Claim 18 (Original). A process according to claim 17, wherein the Gram-negative bacterium is selected from the group consisting of *Escherichia sp.*, *Pseudomonas sp.*, *Enterobacter sp.*, *Erwinia sp.*, *Campylobacter sp.*, *Proteus sp.*, *Aeromonas sp.* and *Vitreoscilla sp.*

Claim 19 (Previously Presented). A process according to claim 17, wherein the Gram-negative bacterium comprises *Escherichia coli*.

Claim 20 (Previously Presented). A process according to claim 1, wherein the recombinant polypeptide is selected from the group consisting of an antibody, a hormone, and an immunomodulating agent.

Claim 21 (Previously Presented). A process according to claim 1, wherein the recombinant polypeptide is selected from the group consisting of a growth hormone, a growth factor, an interferon, a cytokine, an enzyme, an enzyme inhibitor, and an antibody fragment.

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Claim 22 (Previously Presented). A process according to claim 1, wherein the recombinant polypeptide is selected from the group consisting of a Fab-fragment, human growth hormone, interferon alpha-2b, and granulocyte colony-stimulating factor.

Claims 23-29 (Cancelled).